K132828

510(k) Summary for the Elecsys Calcitonin test system

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter Name, Address, Contact

Roche Diagnostics
9115 Hague Road
P.O. Box 50416
Indianapolis, IN 46250-0415

DEC 04 2013

Contact Person: Kelli Turner (Regulatory Affairs Principal)

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Date Prepared: November 25, 2013

Device Name

Proprietary name:
(1) Elecsys Calcitonin Immunoassay
(2) Elecsys Calcitonin CalSet
(3) Elecsys Calcitonin CalCheck 5
(4) Elecsys PreciControl Varia

Common name:
(1) Calcitonin assay
(2) Calcitonin CalSet
(3) Calcitonin CalCheck 5
(4) PreciControl Varia

Classification name:
1) Radioimmunoassay, Calcitonin
2) Calibrator, Secondary
3) Quality control material
4) Quality control material

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510(k) Summary for the Elecsys Calcitonin test system, *continued*

Device Name, *continued*

Product Code:
1) JKR
2) JIT
3) JJY
4) JJY

Predicate Device:
1) Assay: Siemens Immulite 1000 Calcitonin, Model LKCL (k023304)
2) Calibrator: Elecsys Vitamin D CalSet (k113546)
3) Control: Elecsys T4 CalCheck 5 (k112528)
4) Control: Elecsys PreciControl Varia (k111506)

Establishment Registration

For the Elecsys Calcitonin test system, the establishment registration number for Roche Diagnostics GmbH in Mannheim, Germany, is 9610126 and for Penzberg, Germany, is 9610529. The establishment registration number for Roche Diagnostics in the United States is 1823260

Classification

The FDA has classified the Radiometry, Calcitonin test system and the Calibrator, Secondary (Calcitonin CalSet) as a Class II device. The FDA has classified the multi-analyte controls, all kinds (assayed and unassayed) as a Class I device (Calcitonin CalCheck 5 and PreciControl Varia).

Panel	Product Code	Classification Name	Regulation Citation
Clinical Chemistry	JKR	Radioimmunoassay, Calcitonin	21 CFR 862.1140
Clinical Chemistry	JIT	Calibrator, secondary	21 CFR 862.1150
Clinical Chemistry	JJY	Quality Control material	21 CFR 862.1660
Clinical Chemistry	JJY	Quality Control material	21 CFR 862.1660

Analyzer Platform

For the analytical and clinical studies, the **cobas e** 411 was used as the master analyzer.

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510(k) Summary for the Elecsys Calcitonin test system, *continued*

Device Description

The Calcitonin Assay employs monoclonal antibodies specifically directed against hCT. The antibodies labeled with a ruthenium complex and biotin, respectively consist of mouse-specific components.

Results are determined using a calibration curve that is generated specifically on each instrument by a 2 point calibration and a master curve (5-point-calibration) provided with the reagent bar code.

The Elecsys Calcitonin CalSet is a lyophilized product based on buffered equine serum. It has been standardized to IRP WHO Reference Standard 89/620.

The Elecsys Calcitonin CalCheck 5 is a lyophilized product based on buffered equine serum. It has been standardized to IRP WHO Reference Standard 89/620.

The PreciControl Varia is a multi-composite lyophilized 3 level control set which has been previously cleared (k111506), with added calcitonin analyte.

Intended Use/ Indications for Use

Elecsys Calcitonin Reagent:

- The Calcitonin immunoassay is intended for the *in vitro* quantitative determination of human calcitonin (thyrocalcitonin) in serum and plasma. The calcitonin determination is intended to be used as an aid in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism in conjunction with other clinical and laboratory findings.
  The electrochemiluminescence immunoassay "ECLIA" is intended for use on the indicated Elecsys and **cobas e** immunoassay analyzers.

Elecsys Calcitonin CalSet:

- Calcitonin CalSet is used for calibrating the quantitative Elecsys Calcitonin assay on the Elecsys and **cobas e** immunoassay analyzers

Elecsys Calcitonin CalCheck 5:

- The Elecsys Calcitonin CalCheck 5 is an assayed control for use in calcitonin calibration verification and for use in the verification of the calcitonin assay range established by the Elecsys and **cobas e** immunoassay analyzers.

Elecsys PreciControl Varia:

- The Elecsys PreciControl Varia is used for quality control of the Elecsys immunoassays on Elecsys and **cobas e** immunoassay analyzers.

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Substantial Equivalence

The Elecsys Calcitonin Test System is substantially equivalent to other devices legally marketed in the United States.

The Elecsys Calcitonin immunoassay is equivalent to Immulite 1000 Calcitonin (k023304).

Elecsys Calcitonin CalSet is equivalent to Elecsys Vitamin D CalSet (k113546).

Elecsys Calcitonin CalCheck 5 is equivalent to the Elecsys T4 CalCheck 5 (k112528).

Elecsys PreciControl Varia is equivalent to Elecsys PreciControl Varia (k111506).

Substantial Equivalence - Comparison

The following tables compare:

- The Elecsys Calcitonin Immunoassay with its predicate device (k023304).
- The Calcitonin CalSet with its predicate device (k113546).
- The Calcitonin CalCheck 5 its the predicate device (k112528).
- PreciControl Varia to its predicate device (k111506).

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Comparison of Assays, Similarities and Differences

Table 1

Assay Comparison		
Feature	**Predicate Device: Immulite 1000 Calcitonin, Model LKCL (k023304)**	**Elecsys Calcitonin Immunoassay**
General Assay Features		
Intended Use/ Indications for Use	Intended to measure the thyroid hormone calcitonin (thryocalcitonin) levels in serum. Calcitonin measurements are used in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism (excessive activity of the parathyroid gland).	The Calcitonin immunoassay is intended for the in vitro quantitative determination of human calcitonin (thyrocalcitonin) in serum and plasma. The calcitonin determination is intended to be used as an aid in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism in conjunction with other clinical and laboratory findings. The **e**lectro**c**hemi**l**uminescence **i**mmuno**a**ssay "ECLIA" is intended for use on the indicated Elecsys and **cobas e** immunoassay analyzers.
Assay Protocol	A solid-phase, enzyme-labeled, two-site chemiluminescent immunometric assay. The solid-phase, a polystyrene bead enclosed within an IMMULITE 1000 Test Unit, is coated with a monoclonal murine antibody specific for calcitonin. Incubation cycles: 2 x 30 minutes Total duration of assay: 60 minutes.	Assay employs murine monoclonal antibodies specifically directed against hCT. One antibody is labeled with ruthenium complex; the second antibody is labeled with Biotin. Streptavidin coated microparticles are used as solid phase. Sandwich principle. Total duration of assay: 18 minutes
Detection Protocol	Chemiluminescent Immunometric assay	Electrochemiluminescent Immunoassay
Applications	60-minute application	18-minute application

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Comparison of Assays—Similarities and Differences, *continued*

Table 1 ***continued***

Assay Comparison		
Feature	**Predicate Device: Immulite 1000 Calcitonin, Model LKCL (k023304)**	**Elecsys Calcitonin Immunoassay**
General Assay Features		
Instrument Platform	Immulite 1000	**cobas e** 411
Sample Volume	75 µL	50 µL
Sample Type	Human serum or heparinized plasma	Human serum and plasma treated with K_2-EDTA, K_3-EDTA, lithium heparin and lithium heparin plasma gel separation tubes.
Reagents	A solid-phase, enzyme-labeled, two-site chemiluminescent immunometric assay. The solid-phase, a polystyrene bead enclosed within an IMMULITE 1000 Test Unit, is coated with a monoclonal murine antibody specific for calcitonin. Incubation cycles: 2 x 30 minutes Total duration of assay: 60 minutes.	Sandwich principle. Total duration of assay: 18 minutes Assay employs murine monoclonal antibodies specifically directed against hCT. One antibody is labeled with ruthenium complex; the second antibody is labeled with Biotin. Streptavidin coated microparticles are used as solid phase.
Calibrator	Siemens Calcitonin Adjustors (LCLL, LCLH)	Elecsys Calcitonin CalSet

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Comparison of Assays—Similarities and Differences, *continued*

Table 1 ***continued***

Assay Comparison		
Feature	**Predicate Device: Immulite 1000 Calcitonin, Model LKCL (k023304)**	**Elecsys Calcitonin Immunoassay**
General Assay Features		
Calibration Interval	Recommended Adjustment interval: 4 weeks	Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer). Renewed calibration is recommended as follows: **cobas e 411** analyzers: • After 2 months (56 days) when using the same reagent lot. • After 7 days (when using the same reagent kit on the analyzer). As required: e.g. quality control findings outside the specified limits
Controls	Use controls or sample pools with at least two levels (low and high) of calcitonin.	Elecsys PreciControl Varia
Traceability / Standardization	Standardized against WHO 2nd IRP 89/620	Same
Reagent Stability	Stable at 2-8°C until expiration date	Unopened: 2-8°C - Up to the stated expiration date Opened 2-8°C - 12 weeks On Analyzers – 4 weeks

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Comparison of Assays—Similarities and Differences, continued

Table 1 *continued*

Assay Comparison		
Feature	**Predicate Device: Immulite 1000 Calcitonin, Model LKCL (k023304)**	**Elecsys Calcitonin Immunoassay**
Labeled Performance Characteristics		
Measuring Range	0.6 – 2000 pg/mL	1.0 - 2000 pg/mL
Precision	Within-run Sample / Mean / SD / CV 1 / 22 / 0.86 / 3.9% 2 / 44 / 1.3 / 3.0% 3 / 145 / 3.3 / 2.3% 4 / 621 / 13.8 / 2.2% 5 / 1029 / 24.8 / 2.4% 6 / 1207 / 27.4 / 2.3% Total Sample / Mean / SD / CV 1 / 22 / 2.5 / 11.4% 2 / 44 / 3.3 / 7.5% 3 / 145 / 10.9 / 7.5% 4 / 621 / 65.6 / 10.6% 5 / 1029 / 87.3 / 8.5% 6 / 1207 / 115 / 9.5%	***cobas** e 411:* Within-run (will be labeled Repeatability) 0.03 SD @ 1.21 pg/mL 3.0% CV @ 11.5 pg/mL 2.5% CV @ 48.5pg/mL 2.9% CV @ 482 pg/mL 2.2% CV @ 1910 pg/mL 0.19 SD^{PCV1} @ 8.88 pg/mL 1.5% CV^{PCV2} @ 97.7 pg/mL Total (will be labeled Intermediate) 0.04 SD @ 1.21 pg/mL 3.6% CV @ 11.5 pg/mL 3.5% CV @ 48.5pg/mL 4.0% CV @ 482 pg/mL 3.4% CV @ 1910 pg/mL 0.26 SD^{PCV1} @ 8.88 pg/mL 2.6% CV^{PCV2} @ 97.7 pg/mL

PCV1=PreciControl Varia level 1
PCV2=PreciControl Varia level 2

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Comparison of Assays—Similarities and Differences, *continued*

Table 1 ***continued***

Assay Comparison		
Feature	**Predicate Device: Immulite 1000 Calcitonin, Model LKCL (k023304)**	**Elecsys Calcitonin Immunoassay**
Labeled Performance Characteristics		
Analytical Sensitivity	2 pg/mL	Limit of Blank (LoB): = 0.3 pg/mL Limit of Detection (LoD): = 0.5 pg/mL Limit of Quantitation (LoQ): = 1 pg/mL
Hook Effect	There is no high-dose hook effect at concentrations up to 25,000 pg/mL.	There is no high-dose hook effect at concentrations up to 1,000,000 pg/mL.
Limitations	The assay is unaffected by the presence of: • Hemoglobin < 550 mg/dL. • Bilirubin < 200 mg/L • Lipemia < 3000 mg/dL	The assay is unaffected by: • Hemoglobin < 200 mg/dL. • Bilirubin < 66 mg/dL • Lipemia < 2000 mg/dL • Biotin < 40 ng/mL • Rheumatoid factors < 1,200 IU/mL • IgG < 4 g/dL • IgM < 0.7 g/dL • IgA < 1.6 g/dL • In vitro tests were performed on 17 commonly used and 12 special pharmaceuticals. No interference with the assay was found. • In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design.

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Comparison of Assays—Similarities and Differences, continued

Table 1 ***continued***

<table>
<tr><th colspan="3">Immunoassay Comparison</th></tr>
<tr><th>Feature</th><th>Predicate Device: Immulite 1000 Calcitonin, Model LKCL (k023304)</th><th>Elecsys Calcitonin Immunoassay</th></tr>
<tr><th colspan="3">Labeled Performance Characteristics</th></tr>
<tr><td>Method Comparison</td><td colspan="2"><table>
<tr><td>n = 150
Min = 2.04 pg/mL
Max = 1779 pg/mL</td><td>Passing/Bablok</td><td>Deming</td></tr>
<tr><td>Slope</td><td>1.01</td><td>0.998</td></tr>
<tr><td>Intercept</td><td>-0.404</td><td>-0.305</td></tr>
<tr><td>Tau/r</td><td>0.925</td><td>0.991</td></tr>
</table></td></tr>
<tr><td>Clinical Study/ reference range</td><td>95th percentile:
Female 5.0 pg/mL
Male 8.4 pg/mL</td><td>97.5th percentile:
Female 7.63 pg/mL
Male 14.3 pg/mL</td></tr>
</table>

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Comparison of Assays—Similarities and Differences, continued

Table 1 ***continued***

Performance Characteristics		
Elecsys Calcitonin Immunoassay on cobas e 411 (master analyzer)		
Analytic Specificity		
Cross reactant	Max. concentration tested (ng/mL)	Highest cross-reactivity observed (%)
Salmon Calcitonin	200	0.017
Porcine Calcitonin	1000	0.007
Chicken Calcitonin	1000	0.005
ACTH (1-39) human	200	0.037
C-Peptide	80000	0.000
Calcitonin Gene Related Peptide	2000	0.002
PTH (1-84)	300	0.013
TSH	2000µIU/mL	0.009
Insulin	67000	0.000
Prolactin	2000	0.001
Gastrin I	4000	0.001
Elcatonin	200000	0.000
Katacalcin	80000	0.000

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Table 2

Elecsys CalSet comparison		
Feature	**Predicate Device Elecsys Vitamin D CalSet**	**Elecsys Calcitonin CalSet**
Intended Use	Elecsys Vitamin D CalSet is used for calibrating the quantitative Elecsys Vitamin D assay on the Elecsys and **cobas e** immunoassay analyzers.	Calcitonin CalSet is used for calibrating the quantitative Elecsys Calcitonin assay on the Elecsys and cobas e immunoassay analyzers.
Levels	Two	Two
Matrix	Human serum	Buffered (50 mmol/L HEPES) equine serum
Format	Lyophilized	Lyophilized
Stability	Unopened: up to the stated expiration date After reconstituting: At 2-8C – 120 hours At -20C – 90 days (freeze only once) On Elecsys 2010/**cobas e** 411 at 20-25°C: up to 5 hours On MODULAR ANALYTICS E170/**cobas e** 601: Use only once	Unopened: up to the stated expiration date After reconstituting: At 2-8°C – 72 hours At -20°C – 84 days (freeze only once) At 20-25°C: up to 5 hours
Composition	**Buffer:** HEPES 50mM **Preservative:** Bronidox L 0.5%	**Buffer:** HEPES 50mM Human Calcitonin (synthetic)

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Table 3

Elecsys CalCheck comparison		
Characteristic	**Elecsys T4 CalCheck 5 (Predicate Device)**	**Elecsys Calcitonin CalCheck 5**
Intended Use	The Elecsys T4 CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys T4 quantitative assay reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.	The Elecsys Calcitonin CalCheck 5 is an assayed control for use in calcitonin calibration verification and for use in the verification of the calcitonin assay range established by the Elecsys and **cobas e** immunoassay analyzers.
Analyte	T4	Calcitonin
Levels	Five	Five
Assay Measuring Range	0.300 – 10.0 nmol/L	1.0 – 2000 pg/mL
Check Target Values	Check 1: ≤ 10 nmol/L Check 2: 100 nmol/L Check 3: 160 nmol/L Check 4: 250 nmol/L Check 5: 320 nmol/L	Check 1: ≤ 1.00 pg/mL Check 2: 50 pg/mL Check 3: 500 pg/mL Check 4: 1000 pg/mL Check 5: 2000 pg/mL
Format	Lyophilized	Same
Handling	Reconstitute Check 1, Check 2, Check 3, Check 4, and Check 5 with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion.	Same
Stability	Unopened: • Store at 2-8°C until expiration date Reconstituted: • 15-25°C: 4 hours	Unopened: • Store at 2-8°C until expiration date Reconstituted: 20-25°C: 4 hours
Matrix	Level 1: BSA/Buffer matrix Level 2-5: Human serum	Buffered (50 mmol/L HEPES) equine serum

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Table 4

Elecsys PreciControl Varia comparison		
Feature	**Predicate Device Elecsys PreciControl Varia (k111506)**	**Elecsys PreciControl Varia**
Intended Use	Elecsys PreciControl Varia is used for quality control of specified Elecsys immunoassays on the Elecsys and **cobas e** immunoassay analyzers.	Same with the addition of calcitonin analyte.
Analyzer system	Elecsys and **cobas e** immunoassay analyzers.	Same
Format	Lyophilized	Same
Levels	Three	Same
Matrix	Human serum	Same
Format	Lyophilized	Same
Traceability	• β-CrossLaps/serum (β-CTx)—Gravimetry • Osteocalcin—In-house reference system (commercially available osteocalcin immuno/radio-binding assay • Parathyroid Hormone (PTH and PTH STAT)—In-house reference system (commercially available PTH radiobinding assay) • Vitamin B_{12}—Commercially available radio-binding assay • Ferritin—NIBSC Standard 80/602 • Folate—Elecsys Folate II Assay • Vitamin D —LC-MS/MS (which in turn has been standardized to the NIST standard)	• β-CrossLaps/serum (β-CTx)—Gravimetry • Osteocalcin—In-house reference system (commercially available osteocalcin immuno/radio-binding assay • Parathyroid Hormone (PTH and PTH STAT)—In-house reference system (commercially available PTH radiobinding assay) • Vitamin B_{12}—Commercially available radio-binding assay • Ferritin—NIBSC Standard 80/602 • Folate—Elecsys Folate II Assay • Vitamin D —LC-MS/MS (which in turn has been standardized to the NIST standard) • Calcitonin- standardized to IRP WHO Reference Standard 89/620

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Table 4, *continued*

Elecsys PreciControl Varia comparison, *continued*		
Feature	**Predicate Device Elecsys PreciControl Varia**	**Elecsys PreciControl Varia**
Analyte Concentration	• Ferritin (ng/mL) Level 0 = 14 Level 1 = 150 Level 2 = 1000 • Folate (ng/mL) Level 0 = N/A Level 1 = 3.9 Level 2 = 12 • Vitamin B12 (pg/mL) Level 0 = 230 Level 1 = 500 Level 2 = 1000 • β-CTx (pg/mL) Level 0 = N/A Level 1 = 320 Level 2 = 750 • Osteocalcin (ng/mL) Level 0 = N/A Level 1 = 20 Level 2 = 100 • PTH and PTH STAT (pg/mL) Level 0 = 25 Level 1 = 60 Level 2 = 200 • Vitamin D (ng/mL) Level 0 = 12.8 Level 1 = 17 Level 2 = 32	• Ferritin (ng/mL) Level 0 = 14 Level 1 = 150 Level 2 = 1000 • Folate (ng/mL) Level 0 = N/A Level 1 = 3.9 Level 2 = 12 • Vitamin B12 (pg/mL) Level 0 = 230 Level 1 = 500 Level 2 = 1000 • β-CTx (pg/mL) Level 0 = N/A Level 1 = 320 Level 2 = 750 • Osteocalcin (ng/mL) Level 0 = N/A Level 1 = 20 Level 2 = 100 • PTH and PTH STAT (pg/mL) Level 0 = 25 Level 1 = 60 Level 2 = 200 • Vitamin D (ng/mL) Level 0 = 12.8 Level 1 = 17 Level 2 = 32 • Calcitonin (pg/mL) Level 0 = N/A Level 1 = 10 Level 2 = 100

Continued on next page

Table 4, *continued*

Elecsys PreciControl Varia comparison, *continued*		
Feature	**Predicate Device Elecsys PreciControl Varia**	**Elecsys PreciControl Varia**
Handling	Dissolve carefully the contents of one bottle by adding exactly 3.0 mL of distilled or deionized water and allow standing closed for 30 minutes to reconstitute. Mix carefully, avoiding the formation of foam.	Same
Volume (reconstituted)	3.0 mL	Same
Stability	Unopened at 2 – 8 °C: up to the stated expiration date Reconstituted/thawed serum: • at – 20 °C: 31 days (freeze only once) • at 2 – 8 °C: 72 hours • at 20 – 25 °C on-board the analyzers: up to 5 hours	Same

Standard/ Guidance Document Reference

In addition to FDA guidance regarding 510(k) submissions, the following standards were used for the performance studies.

- Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition. CLSI document EP5-A2, Volume 24, No. 25, August 2004.
- Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline. CLSI document EP 17-A, Volume 24, No. 34, October 2004.
- Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline- Second Edition. CLSI document EP17-A2, Volume 32, No. 8, June 2012
- Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline. CLSI document EP6-A, Volume 23, No. 16, April 2003.
- Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline; Approved Guideline. CLSI document EP-09-A2-IR, Volume 22, No. 19, September 2002

Conclusion Statement

The submitted information in this premarket notification supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 4, 2013

ROCHE DIAGNOSTICS
KELLI TURNER
REGULATORY AFFAIRS PRINCIPAL
9115 HAGUE ROAD
INDIANAPOLIS IN 46250-0416

Re: K132828
Trade/Device Name: Elecsys Calcitonin Immunoassay
Elecsys Calcitonin CalSet
Elecsys Calcitonin CalCheck 5
Elecsys PreciControl Varia
Regulation Number: 21 CFR 862.1140
Regulation Name: Calcitonin test system
Regulatory Class: II
Product Code: JKR, JIT, JJY
Dated: September 17, 2013
Received: September 18, 2013

Dear Ms. Turner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

k132828

Device Name

Elecsys Calcitonin Immunoassay, Elecsys Calcitonin CalSet, Elecsys Calcitonin CalCheck 5, Elecsys PreciControl Varia

Indications for Use *(Describe)*

Elecsys Calcitonin Immunoassay:
The Calcitonin Immunoassay is intended for the in vitro quantitative determination of human calcitonin (thyrocalcitonin) in serum and plasma. The calcitonin determination is intended to be used as an aid in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism in conjunction with other clinical and laboratory findings.

Elecsys Calcitonin CalSet:
Calcitonin CalSet is used for calibrating the quantitative Elecsys Calcitonin assay on the Elecsys and **cobas e** immunoassay analyzers.

Elecsys Calcitonin CalCheck 5:
The Elecsys CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the calcitonin assay range established by the Elecsys and **cobas e** immunoassay analyzers.

Elecsys PreciControl Varia:
The Elecsys PreciControl Varia is used for quality control of the Elecsys immunoassays on Elecsys and cobas e immunoassay analyzers.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Yung W. Chan -S